

REMARKS

Claims 1 to 7 and 9 to 12 remain in prosecution with claim 8 cancelled.

1. The Examiner objected to the specification for the reasons noted on Page 2.
Applicants have amended the specification appropriately, herein.
2. The Examiner objected to the Claims under 35 U.S.C. 112, sixth paragraph, for the reasons noted on Page 2.
The Applicants have amended the claims appropriately.
3. The Examiner rejected claims 1 to 4, 6 and 11 under 35 U.S.C. 102(b) as being anticipated by Mersch for the reasons noted on Page 4.

The Mersch patent describes an endoscopic device with a remotely powered radiation source located at the distal end of the endoscope. The laser beam produced by the diode is used to "both coagulate and cut tissue in an endoscopic procedure." (col. 1, lines 53-54, see also line 8) Because of these objectives Mersch can not provide a means to create a diffuse radiation pattern and actually requires having a means for focusing the radiation as shown in Figure 1 by the use of a lens. The present invention is directed providing PhotoDynamic Therapy which requires the opposite irradiation pattern from the aims of Mersch. Its design aim is to create a homogenous radiation pattern using multiple radiation sources and diffusing means at the distal end of the active endoscope. As described in claim 1 of the present invention, the radiation source "provides a diffuse radiation pattern across a section of body tissue, which is large compared to said... distal cross section". (emphasis added) Because Mersch is directed at cutting and coagulating tissue which requires a beam with a sufficient energy density to burn tissue, it thus requires a focused rather than a diffuse beam. All embodiments described in Mersch focus the beam to a distinct point with the aid of focusing means such as a lens. A diffuse beam would render Mersch useless for its disclosed purpose. A focused beam such as that disclosed in Mersch would be potentially dangerous to patients for PDT treatments such as those contemplated by the present invention. Thus, because '238 presents a design aimed at a diametrically opposed treatment regime to the present invention, it can not anticipate a diffuse radiation delivery pattern, of the present invention.

The Examiner notes that "Mersch teaches, "can be at any selected wavelength and can be concentrated, diffused or have any other desired spatial distribution." See col. 7, lines 11 to 14." Applicant does not agree with this statement, and could not find the quote since there is no column 7 in Mersch and nor could the quote be found anywhere else in the actual specification.

Since Mersch is dealing with medical treatments whose power and distribution requirements are diametrically opposed to those of PDT treatments in the present invention Mersch cannot anticipate claims 1-4, 6 and 11 as postulated by examiner.

4. The Examiner has rejected claim 5 under 35 U.S.C. 103(a) as being unpatentable over Mersch in view of Berry for the reasons noted on Page 5.

The Mersch reference does not disclose the use of chemiluminescence and is for medical treatments whose optical power levels and distribution are essentially diametrically opposed to the requirements used in PDT. Berry in the specific reference in column 4 is describing the powering of a flash pumped chemical laser source basically externally to the eye, treatment site. While both a chemical alser and chemiluminescence use chemical reactions, there is no chemist or laser professional who would draw inferences from one area to the other, except that chemical reactions can create light in some cases as well as heat. The size of reactor, energy input and virtually everything that is associate with a chemical laser are tremendous compared the light output, amount of material, etc. needed to create chemiluminescence and use it for activating photosensitizers for PDT. As one who has worked in luminescence-related studies for over 30 years and lasers for over 20 years, I verify that those skilled in the art would not draw any inferences from chemical lasers for any use related to chemiluminescence. As a consequence there is no reason to combine these references since Mersch is concerned with providing intense focused light for cutting and coagulation of tissue with chemical lasers and Berry is discussing photothermal treatment of the tissue not photochemical as in PDT. Further, there is no way that the source of light of Berry, a flash lamp could practically be placed within an endoscopic device.

Claim 5 has been amended to further confirm the chemiluminescence is created at the distal end of the endoscope in present invention, and is clearly patentable over the combination cited.

5. The Examiner has rejected claims 6, 7, 9 10 and 12 under 35 U.S.C. 103(a) as being unpatentable over Mersch in view of Chen et al. for the reasons noted on Page 5.

Mersch discloses a laser diode device with focused beam for cutting and coagulating tissue.

Chen et al. discloses an endoscopic apparatus and method for use in PDT comprising a flexible substrate positioned or positionable at the distal end of a probe for the application of electromagnetic or other energy. The flexible substrate can be delivered into the body and conform to areas or tumors with minimal invasion as shown. Electronic microcircuits are positioned on the substrate to perform a variety of tasks such as photodetection or PDT. For PDT, light sources such as diodes or laser diodes are positioned on the substrate and surrounded by a flexible transparent envelope. Infrared power transmitted to an IR detector can be used to provide electric power from an external source to the substrate.

Chen et al. does disclose a plurality of diodes on the distal end of a probe, but fails to provide means for emitting a diffuse radiation pattern that is large compared to the probe or other substrate. Chen et al. relies on the flexible shape of the substrate to determine the radiation pattern, and thus requires that a special substrate be constructed for each body area or at least is moldable to conform to each body area to be treated. The "flexible substrate changes size and shape as necessary to maintain the light sources in close proximity with the treatment site". (Chen et al., col. 4, line 50) Chen et al. thus produce a variety of differently shaped probes for different body areas which can prove to be time consuming and expensive. In contrast, the present invention provides for a radiation source emitting a large area diffuse radiation pattern that may be used for a more diverse range of treatments. With the present invention, a greater variety of treatment sites may be treated with one embodiment, because the emitted radiation pattern can effectively reach the treatment site without the need for close physical proximity. Although other sources beyond LEDs are disclosed, Chen et al. apparently only contemplates use with light sources that have limited radiation patterns, because all the embodiments are meant to bring the light sources close to tissue. Thus, the present invention is distinct from Chen et al. in that it utilizes a relatively large diffuse radiation pattern to reach tissue, rather than applying a device that conforms in shape to the treated tissue.

Chen et al. describes a number of embodiments, which are briefly described below to illustrate the need for close proximity between the probe and treated tissue, in contrast to the present invention. Figures 1-13 are described in the context of tumor irradiation wherein a tumor is pierced and the probe is guided into a tumor or other solid tissue mass. The light sources on the probe are in close proximity to the diseased tissue. Another example is shown in figures 14-16,

wherein a plurality of flexible probes are splayed outward for treatment of the bladder. These probes, which may also take the form of loops, spread out so that the light sources are in close proximity to the bladder wall. The present invention contemplates irradiating a body cavity such as the bladder with a diffuse radiation pattern, obviating the need for such a complex and specialized device. Also disclosed by Chen et al. are flexible sheet probes, which are folded prior to insertion and unfolded within the body, as is illustrated well in figures 17-21, which further demonstrate that '478 relies on physical proximity, rather than radiation pattern, to provide radiation to a treatment site. Figures 22-26 illustrate embodiments where the sheet probe is rolled prior to insertion and unrolled at the treatment site. Other figures also appear to require inserting the probe so that the light sources are in very close proximity to the treatment site.

A key differentiating point is that Mersch discloses the use of a laser diode to focus energy for cutting and coagulation. It is clear from Chen et al. that the flexible cover does not aid in scattering of the light from the LEDs. See Col. 17, lines 13 to 17. There is no reason to combine Mersch with Chen et al. since they teach different techniques, one cutting and coagulation tissue and the other of providing light to tissue by a light source that is flexible and has a plurality of LEDs thereon.

The balloon of Chen et al. is formed to be a sealing cup and does not function as in the present invention of centering the light radiation source. Claim 9. Further, Chen et al. does not disclose the means for delivery of the photosensitizer through the endoscopic device. Claim 7. It is unclear how Chen et al. teach the use of a reflective coating when it notes that lasers are on both sides of the sheet. See Col. 12, lines 58, to Col. 15, line 3.

With these remarks it is believed that the requirements of 35 USC, 37 CFR and the MPEP have been answered and the disclosure and claims are now in condition for examination as one whole invention. Consideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Respectfully submitted,

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CeramOptec Industries, Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-8222


Bolesh J. Skutnik, PhD, JD
Reg. No. 36,347
Attorney for Applicants
Fax: (413) 525-0611